mark-up

ATTY. DOCKET NO. PRES06-00163 PATENT APPLICATION

TITLE: SEGMENTED SCLERAL BAND FOR TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS

RELATIONSHIP TO OTHER APPLICATIONS

This application is a continuation of prior U.S. Application Serial No. 09/032,830 filed on March 2, 1998, which [This application] is a continuation-in-part of copending application Serial No. 08/462,649, filed June 05, 1995, now U.S. Patent No. 5,722,952, which is a divisional of U.S. application Serial No. 08/139,756, filed, October 22, 1993, now U.S. Patent No. 5,489,299, which is a divisional of U.S. application Serial No. 07/913,486, filed July 15, 1992, now U.S. Patent No. 5,354,331.

[BACKGROUND OF THE INVENTION]

[1. Field of the Invention]

TECHNICAL FIELD OF THE INVENTION

This invention relates to methods of treating presbyopia, hyperopia, primary open angle glaucoma and ocular hypertension and more particularly to methods of treating these diseases by increasing the effective working distance of the ciliary muscle. The invention also relates to increasing the

amplitude of accommodation of the eye by increasing the effective working range of the ciliary muscle [and to prosthetic devices for achieving such increased amplitude of accommodation].

[<u>2. Brief Description of the Prior Art:</u>]

BACKGROUND OF THE INVENTION

In order for the human eye to have clear vision of objects at different distances, the effective focal length of the eye must be adjusted to keep the image of the object focused as sharply as possible on the retina. This change in effective focal length is known as accommodation and is accomplished in the eye by varying the shape of the crystalline lens. Generally, in the unaccommodated emmettopic eye the curvature of the lens is such that distant objects are sharply imaged on the retina. In the unaccommodated eye, near objects are not focused sharply on the retina because their images lie behind the retinal surface. In order to visualize a near object clearly, the curvature of the crystalline lens is increased, thereby increasing its refractive power and causing the image of the near object to fall on the retina.

The change in shape of the crystalline lens is accomplished by the action of certain muscles and structures within the eyeball or globe of the eye. The lens is located

in the forward part of the eye, immediately behind the pupil. It has the shape of a classical biconvex optical lens, i.e., it has a generally circular cross section having two convex refracting surfaces, and is located generally on the optical axis of the eye, i.e., a straight line drawn from the center of the cornea to the macula in the retina at the posterior portion of the globe. In the unaccommodated human eye the curvature of the posterior surface of the lens, i.e., the surface adjacent to the vitreous body, is somewhat greater than that of the anterior surface. The lens is closely surrounded by a membranous capsule that serves as an intermediate structure in the support and actuation of the lens. The lens and its capsule are suspended on the optical axis behind the pupil by a circular assembly of very many radially directed [elastic] <u>collagenous</u> fibers, the zonules, which are attached at their inner ends to the lens capsule and at their outer ends to the ciliary body, a muscular ring of tissue[,] located just within the outer supporting structure of the eye, the sclera. The ciliary body is relaxed in the unaccommodated eye and therefore assumes its largest diameter. According to the classical theory of accommodation, originating with Helmholtz, the relatively large diameter of the ciliary [muscle] <u>body</u> in this condition causes a tension on

the zonules which in turn pull[s] radially outward on the lens capsule, causing the equatorial diameter of the lens to increase slightly and decreasing the anterior-posterior dimension of the lens at the optical axis. Thus, the tension on the lens capsule causes the lens to assume a flattened state wherein the curvature of the anterior surface, and to some extent of the posterior surface, is less than it would be in the absence of the tension. In this state the refractive power of the lens is relatively low and the eye is focused for clear vision of distant objects.

When the eye is intended to be focused on a near object, the [ciliary] muscles <u>of the ciliary body</u> contract. According to the classical theory, this contraction causes the ciliary [muscle] <u>body</u> to move forward and inward, thereby relaxing the outward pull of the zonules on the equator of the lens capsule. This reduced zonular tension allows the elastic capsule of the lens to contract, causing an increase in the antero-posterior diameter of the lens (i.e., the lens becomes more spherical) resulting in an increase in the optical power of the lens. Because of topographical differences in the thickness of the lens capsule, the central anterior radius of curvature decreases more than the central posterior radius of curvature. This is the accommodated condition of the eye wherein the image of

near objects falls sharply on the retina.

Presbyopia is the universal decrease in the amplitude of accommodation that is typically observed in individuals over 40 years of age. In the person having normal vision, i.e., having emmetropic eyes, the ability to focus on near objects is gradually lost, and the individual comes to need glasses for tasks requiring near vision, such as reading.

According to the conventional view the amplitude of accommodation of the aging eye is decreased because of [the] loss of elasticity of the lens capsule and/or sclerosis of the lens with age. Consequently, even though the radial tension on the zonules is relaxed by contraction of the [ciliary] muscles <u>of the ciliary body</u>, the lens does not assume a greater curvature. According to the conventional view, it is not possible by any treatment to restore the accommodative power to the presbyopic eye. The loss of elasticity of the lens and capsule is seen as irreversible, and the only solution to the problems presented by presbyopia is to use corrective lenses for close work, or bifocal lenses, if corrective lenses are also required for distant vision.

Certain rings [and/or segments] have been used in ocular surgery for various purposes. Rings [and/or segments] of flexible and/or elastic material, [attached or] prepared in situ

by fastening the ends of strips of the material around the generally posterior portion of the globe, [posterior to the pars plana (over the underlying retina),] have been used to compress the sclera in certain posterior regions. Supporting rings of metal, adapted to fit the contour of the sclera have been used as temporary supporting structures during surgery on the globe. However, none of these known devices have been used for surgical treatment of presbyopia, and none [has] have been adapted to the special needs of prosthetic devices used in treating presbyopia.

A sceral band adapted to be fastened to the sclera of the eye in the region of the ciliary body in order to expand the sclera in that region and thereby increase the working distance of the ciliary muscle is described in applicant's U.S. Patent No. 5,354,311, the entire disclosure of which is incorporated herein by reference. The scleral band of that patent is manufactured as a single unitary device that is placed on the surface of the sclera and fastened thereto, e.g., by suturing. Although the band is effective, alternate designs are possible that permit greater flexibility in installing the scleral band.

[Accordingly, a need has continued to exist for a scleral band for treating presbyopia and other eye disorders that

allows the surgeon the opportunity of other methods of installing or implanting the band.]

Accordingly, a need has continued to exist for a method of treating presbyopia that will increase the amplitude of accommodation of the presbyopic eye, thereby lessening or eliminating the need for auxiliary spectacle lenses to relieve the problems of presbyopia.

SUMMARY OF THE INVENTION

[An alternative design for a scleral band that can be implanted to treat presbyopia and other eye disorders if found in the band of this invention wherein a scleral band comprises a plurality of segments that can be assembled on the eye to form a complete scleral band. The invention also comprises a method for installing such a segmented band comprising the steps of forming tunnels in the substance of the sclera in the region overlying the ciliary body, inserting segments of the segmented band into the tunnels, and uniting the ends of the segments to form a unitary scleral band.]

A method of treating presbyopia and other eye disorders has now been found which comprises increasing the effective working distance of the ciliary muscle in the presbyopic eye.

Accordingly, it is an object of the invention to provide

a [treatment for] method for treating presbyopia.

A further object is to provide a [treatment for] method for treating presbyopia by increasing the effective working distance of the ciliary muscle in the presbyopic eye.

A further object is to provide a [treatment for] method for treating presbyopia by increasing the radial distance between the equator of the crystalline lens and the ciliary body.

[A further object is to provide a treatment for presbyopia by implanting in the sclera in the region overlying the ciliary body a generally rigid band whereby the sclera is expanded in the region of the ciliary body.]

[A further object is to provide a segmented scleral band that can be assembled on the eye to provide a generally rigid band.]

[A further object is to provide a segmented scleral band having segments that can be inserted into tunnels prepared in the substance of the sclera and assembled thereafter to provide a generally rigid band.]

A further object is to provide a method of treating presbyopia by suturing a scleral expansion band to the sclera of the globe at the location of the ciliary body.

A further object is to provide a method of treating presbyopia by weakening the sclera in the region of the ciliary

body.

A further object is to provide a method of treating presbyopia by arresting the growth of the crystalline lens in the presbyopic eye.

A further object is to provide a method of treating presbyopia by shortening the zonules in the presbyopic eye.

A further object is to provide a method of treating presbyopia by shortening the ciliary muscle or moving its insertions.

A further object is to provide a treatment for hyperopia.

A further object of the invention is to provide a treatment for primary open angle glaucoma.

A further object is to provide a treatment for ocular hypertension.

A further object is to provide a method for increasing the amplitude of accommodation of the eye.

Further objects of the invention will become apparent from the description of the invention which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

[Figure 1 illustrates a front elevational view of human eye with a scleral expansion band of the invention implanted therein.]

FIGURE 1 shows an isometric view of a scleral expansion band of this invention;

[Figure 2 shows a cross-section of the eye shown in Figure 1 along the line 2-2.]

FIGURE 2 shows an anterior elevational view of the band of FIGURE 1;

[Figure 3 shows an enlarged view of the cross section of Figure 4 in the region indicated by the circle 3.]

FIGURE 3 shows a posterior elevational view of the band of FIGURE 1;

[Figure 4 shows a front elevational view of the segmented scleral band of the invention.]

FIGURE 4 shows a side view of the band of FIGURE 1;

[Figure 5 shows a side elevational view of the band.]

FIGURE 5 shows a lateral sectional view of the band of FIGURE 2;

[Figure 6 shows an isometric view of the band.]

FIGURE 6 shows a posterior elevation view of another embodiment of the scleral expansion band of the invention which

uses pins for fixation;

[Figure 7 shows a plan view of a segment of the band.]

FIGURE 7 shows a lateral sectional view of the band of FIGURE 6;

[Figure 8 shows an end view of a band segment as indicated by line 8-8 in Figure 7.]

FIGURE 8 shows a posterior elevation view of another embodiment of the scleral expansion band of the invention which uses tangentially extending fixation pins;

[Figure 9 shows an end view of a band segment as indicated by line 9-9 in Figure 7.]

FIGURE 9 shows a lateral sectional view of the band of FIGURE 8;

[Figure 10 shows a cross-sectional view of band segment along line 10-10 in Figure 7.]

FIGURE 10 shows a diagram of an exemplary laser of the type capable of treating various eye diseases in accordance with the principles of the present invention; and

[Figure 11 shows a cross section of the fused tongue and groove portion of the segmented scleral band along lines 11-11 in Figure 4.]

FIGURE 11 shows an exemplary flow diagram of an exemplary method of operating a laser in accordance with the principles of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[AND PREFERRED EMBODIMENTS]

This invention is based on a theory of presbyopia different from the classical theory of Helmholtz. Although the scope of the invention is not to be bound or limited by the inventor's theory, it is the inventor's view that the presbyopic loss of accommodation is due to decreased working distance of the ciliary muscle. This theory is described in more detail in Patent No. 5,354,331, referenced above and incorporated herein by reference. Consequently, according to the invention, presbyopia is treated by increasing the effective working distance of the ciliary muscle. This is accomplished by increasing the distance between the ciliary muscle and the lens equator by increasing the diameter of the sclera in the region of the ciliary body.

[According to the invention, the effective working distance of the ciliary muscle is increased by implanting in tunnels or pockets surgically formed within the tissue of the sclera of the eye a plurality of scleral band segments. The

segments are then joined to form a complete scleral expansion band implanted at least partially within the sclera of the eye. The completed scleral expansion band is sized to be slightly larger than the sclera in the region of the ciliary body. Accordingly, the scleral expansion band exerts an outward traction on the sclera, thereby expanding it slightly generally in the plane of the crystalline lens. The scleral expansion also expands, i.e., increases the diameter, of the ciliary body which lies immediately inside or beneath the sclera and is anatomically attached thereto.]

[The relevant anatomy of the eye for understanding the operation of the scleral expansion band of the invention and for locating the scleral pockets may be seen by reference to Figures 1-3. Figure 1 shows an eye 100 provided with a scleral expansion band according to the invention. The outermost layer of the eye 100 comprises the white, tough sclera 102 which encompasses most of the globe and the transparent cornea 104, which constitutes the anterior segment of the outer coat. The circular junction of the cornea and sclera is the limbus 106. Within the globe of the eye, as illustrated in the cross-section of Figure 2, taken along line 2-2 in Figure 1, the crystalline lens 108 is enclosed in a thin membranous capsule and is located immediately posterior

to the iris 112, suspended centrally posterior to the pupil 114 on the optical axis of the eye. The lens 108 is suspended by zonules 115 extending between the lens capsule at the equator 110 of the lens 108 and the ciliary body 116. The ciliary body 116 lies just under the sclera 102 (i.e., just inwardly of the sclera 102) and is attached to the inner surface of the sclera 102. As may be seen in Figure 2, the ciliary body 116 lies generally in a plane 130 defined by the equator 110 of the lens 108. The plane 130 can also be extended to intersect the sclera 102 whereby it forms a generally circular intersection located about 2 millimeters posterior to the limbus 106.]

[According to the invention a generally outwardly directed traction is exerted on the sclera in the region of the ciliary body to expand the sclera 102 in that region. This expansion of the sclera 102 produces a corresponding expansion of the attached ciliary body 116 and moves the ciliary body 116 outwardly away from the equator of the lens 108, generally in the plane 130 of the equator 110 of the lens 108. The sclera 102 is preferably expanded approximately in the plane of the equator of the lens 108. However, any expansion of the sclera 102 in the region of the ciliary body 116, i.e., in the region or zone of the sclera extending somewhat anterior or

posterior to the plane of the equator 110 of the lens 108 is within the scope of the invention, provided that such expansion of the sclera 102 moves the ciliary body 116 away from the equator 110 of the lens 108. Typically, the expansion of the sclera will be accomplished in the region or zone from about 1.5 millimeters anterior to the plane 130 of the equator of the lens 108 to about 2.5 millimeters posterior to that plane, i.e., from about 0.5 millimeters to about 4.5 millimeters posterior to the limbus 106. Accordingly, the scleral pocket or tunnel 120 will be located in that region or zone of the sclera.]

[The scleral band 200 of the invention is assembled from a plurality of segments 202. The assembled band 200, as seen in Figures 1, 4, 5 and 6, has an anterior rim 226, a posterior rim 228 and a web structure 230 connecting the two rims. In order to apply to desired outward traction on the sclera at the region of the ciliary body, at least a circumferential portion of the band, i.e., either the anterior rim 226, the posterior rim 228, or the connecting web structure 230, is designed to have a diameter, when the band is assembled, slightly greater than the diameter of the sclera at the location where the band is implanted. Of course, the entire band may have a size slightly greater than the sclera. The

outward tension on the sclera is applied in the region of the ciliary body as illustrated in Figures 2, which shows a cross-section of the eye with the scleral band 200 of the invention implanted, and in Figure 3, which shows a detail of the cross-section of the eye as indicated by the dashed circle 3 in Figure 2. The scleral expansion band 200 is shown within the scleral tunnel 120, which has a base 126, an outer flap 128, an anterior margin 122 and a posterior margin 124. The scleral band 200 within the tunnel or pocket 120 exerts an outward force on the outer flap 128 of the scleral pocket 120 because the band is generally larger in diameter than the sclera at the zone where the band is implanted. The outer flap 128 then transfers the outward traction via its connection to the rest of the sclera at the anterior margin 122 and posterior margin 124. Thereby, the sclera is expanded in a zone surrounding the ciliary body 116 and causes the attached ciliary body 116 to be increased in diameter as well. Accordingly, the scleral pockets or tunnels 120, which resemble belt loops through which the scleral expansion band is threaded, are located in the region of the ciliary body, and generally close to a plane defined by the equator of the crystalline lens. Thus, the scleral expansion band is positioned with respect to the antero-posterior axis of the

globe of the eye, such that it will exert a traction on the sclera that will produce a radial expansion of the ciliary body located just beneath or within the sclera.]

[The scleral band and its segments are illustrated in Figures 4-11 of the drawings wherein the reference numerals refer to the same parts throughout. The scleral band 200 is comprised of a plurality of segments 202. The band 200 is designed to be applied to the sclera of the eye by forming scleral pockets or tunnels in the sclera, then passing a segment 202 through each of the tunnels and fastening the ends of the segments together to form a complete band.]

[Accordingly, each segment 202, as shown in Figures 9-10, has an anterior edge 204, a posterior edge 206, an outer surface 208, an inner surface 210, and two lateral ends 212 and 214. Although the illustrated embodiment of the segment shows a continuous web 230 of material connecting the anterior edge 204 and the posterior edge 206, the connecting structure 230 need not be such a continuous structure. Any structure, e.g., a web having apertures, or a lattice structure, is suitable, provided that the connecting structure has sufficient strength to keep the anterior edge 204 and the posterior edge 206 in their relative positions to provide the necessary rigidity to the assembled band 200. In the

illustrated embodiment, one lateral end 212 of each segment 202 is provided with a tongue 216, and the other lateral end 214 is provided with a corresponding groove 218. After the segments are inserted through the scleral tunnels, the ends 212 and 214 are exposed as shown in Figure 1. Each tongue 216 is then inserted into its corresponding groove 218, and the tongues 214 are then fastened in place within the grooves 218 to form the complete scleral band as shown in Figures 1, 4, and 5. Any means of fastening the segments 202 together is suitable. The segments may be bonded with an adhesive or welded or fused together, or a mechanical fastener, such as a screw or rivet can be used to fasten the ends of the segments 202 together. A preferred method of fastening the segments 202 together, when the segments are made from a preferred plastic material such as poly(methyl methacrylate) is to weld or fuse the lower surface 218 of the tongue 216 to the bottom 222 of the groove 220 by ultrasonic welding. The ultrasonic welding can be accomplished by conventional techniques. For example, the tongue 216 can first be positioned in the groove 220, then a support shoe is inserted under the end 214 of the segment 202 and an ultrasonic welding tool is applied to the tongue 216 for a time sufficient to form a fused welded area 224 (Figure 11).]

[The segments 202 are typically dimensioned to fit snugly in the scleral tunnels. A typical segment will have a width of about 2 millimeters and a thickness of about 0.25 millimeters. The length of a typical segment, measured along the circumference from one end of the main body of the segment 202 to the other will be about 13 millimeters. The tongue will be about 3 millimeters in length. The skilled practitioner will understand that the dimensions will be adapted to the particular eye into which the scleral band is to be implanted. In particular, an assortment of lengths is typically made available to the surgeon so that segments can be selected that, when assembled on the globe of the eye, the completed scleral expansion band will be of the proper size to exert the desired outward traction on the sclera and ciliary body. If the segments 202 are made of a material that has some flexibility perpendicular to the surface thereof, e.g., a synthetic resin material, the segments can be made flat and curved to match the curvature of the globe of the eye when the band is implanted. If the band is made of a more rigid material it is preferable to form an appropriate curve before insertion. A typical segment of the preferred embodiment as illustrated will have a radius of curvature of the anterior rim of about 8.3 millimeters, and a corresponding radius of

curvature of the posterior rim of about 10.3 millimeters. The radii of the rims can be accommodated to the particular dimensions of the eye into which the band is to be implanted.]

[Although the illustrated embodiment shows a tongue-and-grove design for joining the segments 202 that form the scleral band 200, the skilled practitioner will understand that other designs can be used as well. For example a simple butt joint effected by adhesive joining or welding could be used. Similarly, a lap joint or a tapered scarf joint can be used. Again one end of the segment 202 can be provided with a projection that fits into a recess or hole in end of the adjacent segment. The ends can be shaped to have complementary shapes that fit together much as the pieces of a jigsaw puzzle.]

[In practicing the method of the invention, the surgeon first locates the proper region or segment or zone of the sclera to be expanded by measuring a distance of preferably 2.0 millimeters posterior of the limbus. The scleral tunnels or pockets are then formed, preferably by the following procedure. At 2.5 millimeters clockwise and counterclockwise from each of the 45° meridians of the eye, and 2 millimeters posterior to the limbus, partial scleral thickness radial incisions, i.e., antero-posterior incisions, are made which

are 2 millimeters long and 350 microns deep. Using a lamella blade the sclera is dissected until the partial thickness incisions are connected so that four scleral pockets or belt loops are made which have an anterior length of 5 millimeters, and a length extending generally axially of the eye of 2 millimeters. Thus, each pocket or belt loop is preferably centered over the 45° meridian of the eye. Each tunnel is directed generally circumferentially with respect to a circle defined generally by the intersection of the sclera with the plane of the equator of the crystalline lens, although the tunnels need not be exactly in that plane. A segment 202 of the scleral band 200 is then inserted in each pocket so that the ends 212 and 214 of the segments 202 meet in the spaces between the pockets, as shown in Figure 1. The ends 212 and 214 of the segments 202 are then joined. In the illustrated embodiment the ends are joined by fitting the tongue 216 of one segment 202 into the groove 220 of the adjacent segment and fastening the tongue in the groove by ultrasonic welding or other joining technique as discussed above. The completed scleral band then produces symmetrical scleral expansion which will produce the desired result of increasing the effective working distance of the ciliary muscle.]

[The illustrated embodiment of the invention illustrates a

preferred embodiment of the invention using use of four scleral tunnels and four scleral band segments. Fewer or more tunnels may be used at the surgeon's choice. It is not excluded that a single tunnel could be used with the segments of the band being joined through appropriate incisions.]

[The scleral band of the invention is made of a material that is sufficiently rigid to exert a force on the sclera sufficient to produce the radial expansion required by the method of the invention and that is physiologically acceptable for long-term implantation or contact with the ocular tissues. Such materials are well-known in the surgical art and include suitable metals, ceramics, and synthetic resins. Suitable metals include titanium, gold, platinum, stainless steel, tantalum, shape-memory alloys, and various surgically acceptable alloys, and the like. Suitable ceramics may include crystalline and vitreous materials such as porcelain, alumina, silica, silicon carbide, high-strength glasses and the like. Suitable synthetic materials include physiologically inert materials such as poly(methyl methacrylate), polyethylene, polypropylene, poly(tetra-fluoroethylene), polycarbonate, silicone resins and the like. The segment may also be made of composite materials incorporating a synthetic resin or other matrix reinforced

with fibers of high strength material such as glass fibers, boron fibers or the like. Thus, the segment may be made of glass-fiber-reinforced epoxy resin, carbon fiber-reinforced epoxy resin, carbon fiber-reinforced carbon (carbon-carbon), or the like. A preferred material for the segment 202 is surgical grade poly(methyl methacrylate).]

[The segment of the scleral band of the invention may be manufactured by any conventional technique appropriate to the material used, such as machining, injection molding, heat molding, compression molding and the like.]

[The use of the scleral band of the invention to expand the sclera in the region of the ciliary body and increase the working distance of the ciliary muscle may also be of benefit in treatment of hyperopia in certain patients. Some youthful hyperopes can achieve relatively normal vision by compensating for their hyperopia through the natural accommodative ability of the eye. However, as this ability declines with age, they find that it becomes more difficult to attain normal vision by this process, and they begin to experience headaches and other symptoms, even at an age somewhat less than usual for the onset of presbyopia. Evidently, increasing the amplitude of accommodation by the method of this invention would be useful in restoring the ability of these patients to compensate for

their hyperopia.]

[The method of this invention also has utility in the treatment of primary open-angle glaucoma, which shows a correlation with age in certain individuals. It has been found that, in general, intraocular pressure (IOP) exhibits a linear increase with increasing age. (Armaly, M.F., On the distribution of applanation pressure I. Statistical features and the effect of age, sex, and family history of glaucoma, Archives of Ophthalmology, Vol. 73, pp. 11-18 (1965)). Among the general population is found a group of individuals who develop abnormally high intraocular pressures as a result of primary open angle glaucoma, a disease which is one of the most prevalent causes of blindness in the world. According to the theory of this invention, the linear increase in IOP with age is a direct result of the decrease in distance between the lens equator and the ciliary muscle and the resulting linear decrease in the effective pull of the ciliary muscle. Since the ciliary muscle inserts into the trabecular meshwork, the decrease in pull will decrease the size of the trabeculum and/or the drainage pores and result in a linear increase of intraocular pressure with age. In this view, the patients who develop primary open angle glaucoma may have a congenital predilection to narrower pores, protein deposition in the

pores, and/or a smaller trabecular meshwork, so that when the ability of the ciliary muscle to exert force declines, after the age of 40 or thereabouts, they tend to develop excessively elevated IOP.]

[The use of the scleral band of the invention to increase the effective working distance of the ciliary muscle, and thereby increase the force that it can exert when it contracts, restores the level of force which the ciliary muscle exerts on the trabecular meshwork to a value characteristic of a more youthful eye. In this way it is expected that the tendency of an eye that is disposed to develop primary open angle glaucoma as it ages would be overcome and the onset of this disease would be prevented or at least postponed.]

This invention is based on a theory of presbyopia, developed by the inventor, regarding the cause of the loss of amplitude of accommodation that constitutes presbyopia. According to this view, accommodation in the non-presbyopic eye is not due to relaxation of the lens and capsule when the zonular tension is relaxed as a result of the contraction of the ciliary body. On the contrary, the contraction of the ciliary body, exerts a tension on the zonular fibers that in turn actually results in an increase in the equatorial diameter of the lens. However, the

increased zonular tension causes a decrease in the peripheral volume of the lens that in turn results in a corresponding increase in the central volume of the lens. These regional volume changes in the lens are responsible for the change in optical power of the lens. This view differs from all previous theories of the mechanism of accommodation and its loss in presbyopia, in particular from Tscherning's theory which required the vitreous and attributed presbyopia to an enlargement of the nucleus of the lens. From the inventor's point of view, the difference between the change in the central anterior radius of curvature and the change in the central posterior radius of curvature which occurs in accommodation is explained by the force distribution generated by the zonular attachment to the lens and is not dependent on the topographical thickness of the elastic capsule of the lens, the vitreous, or pressure changes which occur between the anterior and posterior chambers, explanations which have been proposed in the prior art. According to the theory of this invention, presbyopia results when the distance between the ciliary body and the equator of the lens and its capsule becomes less with age as a result of the normal growth of the lens. The lens, being of ectodermal origin, continues to grow throughout life, albeit slowly. The rate of increase of the equatorial diameter is approximately 0.02 millimeters per year. On the other hand, the

dimensions of the scleral shell of the eye, which is of mesodermal origin, do not increase significantly after about age 13 in a normally emmetropic, hyperopic or myopic eye. Consequently, the radial distance between the equator of the lens and capsule and the ciliary body, i.e., the distance measured perpendicularly to the optical axis in the plane of the ciliary body, decreases throughout life. It is well known in muscle physiology that as the length of the effective range of pull of a muscle, i.e., its effective working distance, is reduced, its effective force is reduced in a linear fashion. Since the distance between the ciliary body and the lens equator is decreasing throughout life, it is to be expected according to the theory of the invention that there would be a corresponding linear decrease in the amplitude of accommodation, as observed (Alpern, M., in The Eye, H. Dayson, Ed., Academic Press, New York, 1969, pp. 237-238), which would lead eventually to presbyopia.

According to the invention presbyopia is treated by increasing the effective working distance of the ciliary muscle. A number of procedures are available to the surgeon which can accomplish this increase in effective working distance.

A straightforward method of increasing the effective working distance of the ciliary muscle is to increase the distance between the equator of the crystalline lens and the inner

diameter of the ciliary body in the presbyopic eye. This increased distance restores, at least to some extent, the distance through which the muscles of the ciliary body can contract, and thereby restores their ability to exert force on the lens and change its shape to accomplish accommodation. Any method that increases the radial distance between the lens and the ciliary body is effective in the method of this invention.

The effective working distance of the ciliary muscle can also be increased by shortening the zonules that connect the ciliary muscle to the equator of the crystalline lens. Similarly, procedures that shorten the body of the ciliary muscle itself or move its insertions in the scleral spur and the choroid can be employed to increase the effective working distance of the muscle. Finally, procedures that arrest the growth of the lens can stop the steady loss of amplitude of accommodation, and such procedures are considered as fully within the scope of this invention.

It is preferred to increase the lens-ciliary body radial distance by increasing the diameter of the sclera in the region of the ciliary body. Any method that can accomplish such an increase in the diameter of the sclera is considered to fall within the scope of the invention.

A preferred method of increasing the diameter of the sclera in the region of the ciliary body is to fasten to the sclera in

that region a relatively rigid band having a diameter slightly larger than the section of the globe of the eye in the region of the ciliary body. In this way the sclera in that region is stretched and expanded so that the diameter of the circle describing the intersection of the plane of the ciliary body with the sclera is slightly increased. The ciliary body, located immediately inside the globe and attached to the sclera in this expanded region is thereby also increased in diameter.

Thus, the scleral expansion band of the invention adapted for fastening to the sclera of a human eyeball in the region of the ciliary body comprises an anterior rim and a posterior rim, the anterior rim being sized to lie adjacent to the anterior portion of a segment of the sclera of the human eyeball overlying the ciliary body of the eyeball and the posterior rim being sized to lie adjacent the posterior portion of the scleral segment, and rigid structural means extending between the rims and spacing said rims apart so that the anterior rim will lie outside the anterior portion of the scleral segment when the posterior rim lies outside the posterior portion of said scleral segment. The anterior rim, the posterior rim and/or the rigid structural means connecting the rims has a diameter greater than the exterior diameter of the scleral segment adjacent thereto.

Thus, the scleral expansion band of the invention is adapted

to be fitted to the sclera of the globe in the region of the ciliary body. The band will have, at least in part, a diameter slightly greater than that of the sclera at the location where it is to be attached. When the band is fitted to the sclera and firmly attached thereto it will exert a radially outward tension on the sclera which expands the sclera and the underlying ciliary body. The scleral expansion band of the invention may be fastened to the sclera by any conventional surgical method. For example, the band may be a smooth solid band and be sutured to the sclera with sutures passing around the body of the band. A preferred band of the invention is provided with suturing holes through which the sutures may be passed. The band may also be fastened with conventional surgical staples or clips as are well known in the ocular surgery art. The band may be provided with projections or cut-out portions that can be used as anchoring points for sutures. The band may also be provided with projecting pins or the like which are inserted into or under the sclera to position the band and exert the appropriate radially outward tension. These pins may extend in an anterior and/or a posterior direction from the band, and may project from one or both rims of the band or from the web portion connecting the rims. The pins may also project in a generally tangential direction from the rims or the inside of the web and be provided with sharpened tips or the like

whereby they will the penetrate the sclera when the band is rotated and cause the sclera to be firmly fixed to the band and expanded. The band may also be adhesively fastened to the sclera with any physiologically acceptable surgical adhesive. A preferred surgical adhesive is a surgical grade cyanoacrylate adhesive. Mussel adhesive protein may also be used as a suitable adhesive.

A preferred embodiment of the scleral expansion band of the invention is illustrated in FIGS. 1-5. The band 102 has a low frustoconical shape and has a posterior rim 106 and an anterior rim 108, with a web 104 extending between the rims. The band may be provided with one or more holes 110 to assist in suturing the band to the sclera. The anterior rim 106 and the posterior rim 108 are both of generally circular shape. The taper in the diameter of the band is preferably selected in an individual case to fit the globe in the region of the ciliary body. Accordingly, a preferred band has a low frustoconical having a circular base about 20 millimeters in diameter. The radial thickness of the band will be determined by the rigidity required in the band and the strength of the material from which it is made. Typically the radial thickness of the band will be about 0.1 to 0.75 millimeters depending on the rigidity of the substance used to make the band. The diameter of the anterior rim 106 of the band

will be determined by the size of the globe in the patient to be treated. Accordingly, different sizes of band are available wherein the lesser diameter ranges from about 14.5 millimeters to about 18.0 millimeters in 0.25 millimeter increments. The axial width of the band will typically be about 2 millimeters.

An alternate embodiment of the scleral expansion band of the invention adapted to be fixed to the sclera by pins is illustrated in FIGS. 6 and 7. In this embodiment posterior pins 112 are fixed to the band and extend therefrom in a posterior direction while anterior pins 114 extend in an anterior direction.

Another embodiment of the band of the invention using interior tangentially-directed pins 114 is illustrated in FIGS. 8 and 9. This embodiment can be easily installed by placing it in position on the globe and rotating it to cause the tangential pins to penetrate the sclera and fasten it firmly to the band. This embodiment can be easily removed at a later time by merely rotating it in the opposite direction to withdraw the pins from the sclera.

The scleral expansion band of the invention is made of a material that is sufficiently rigid to exert a force on the sclera sufficient to produce the radial expansion required by the method of the invention and that is physiologically acceptable

for long-term implantation or contact with the ocular tissues. Such materials are well-known in the surgical art and include suitable metals, ceramics, and synthetic resins. Suitable metals include titanium, gold, platinum, stainless steel, tantalum and various surgically acceptable alloys, and the like. Suitable ceramics may include crystalline and vitreous materials such as porcelain, alumina, silica, silicon carbide, high-strength glasses and the like. Suitable synthetic resins include physiologically inert materials such as poly(methyl methacrylate), polyethylene, polypropylene, poly(tetrafluoroethylene), silicone resins and the like. The band may also be made of composite materials incorporating a synthetic resin or other matrix reinforced with fibers of high strength material such as glass fibers, boron fibers, carbon fibers, alumina fibers or the like. Thus, the band may be made of glass-fiber-reinforced epoxy resin, carbon fiber reinforced epoxy resin, carbon fiber reinforced carbon (carbon-carbon), or the like. A preferred material is surgical grade poly(methyl methacrylate).

The scleral expansion band of the invention may be manufactured by any conventional technique appropriate to the material used, such as machining, injection molding, heat molding and the like.

The scleral expansion band may also be made in a plurality of parts that can be assembled prior to use or may be installed separately to form a complete band. The band may be adjustable in circumference. For example the band may be formed from a strip of material, e.g., metal or synthetic resin, with overlapping ends so that the ends may slide past one another thereby adjusting the circumference of the band. The length of the overlap may be adjusted, for example, by means of a tangential screw mechanism to adjust the circumference of the band and thereby the amount by which the sclera is expanded.

In practicing the method of the invention, the surgeon locates the proper region of the sclera to be expanded by measuring a distance of 1.5 millimeters posterior of the limbus. At this point the diameter of the circle of sclera surrounding the ciliary body is carefully measured and a band is selected having a minor diameter about 0.5 millimeter greater than the measured diameter. A circular incision is made through the conjunctiva completely around the globe at the selected region and the conjunctiva and Tenon's capsule are reflected to expose the substance of the sclera. For greatest accuracy in positioning the scleral expansion band, the diameter of the sclera as exposed by the reflection of the conjunctiva and Tenon's capsule is measured at a point 1.5 mm posterior to the limbus. Alternatively

the size of sclera can be measured before the conjunctiva is incised. The band is then placed on the surface of the globe and sutured thereto preferably with interrupted stitches as conventional in ophthalmological surgery. In order to facilitate suturing the band to the sclera, the band may be perforated with holes. For example, a total of sixteen holes may be placed equidistant around the band.

It is also possible to expand the sclera in the region of the ciliary body by positioning a band within or just inside the sclera, the band having a diameter just greater than the natural diameter of the overlying tissue. In this way the interior band will expand the overlying tissue and produce the desired result of increasing the effective working distance of the ciliary muscle.

Other methods for increasing the diameter of the sclera in the region of the ciliary body may also be used in the treatment of presbyopia according to the invention. The sclera itself is a tough strong capsule comprised largely of collagen and held in a rigid state of tension by the internal ocular pressure (IOP). If the sclera is weakened in the area adjacent to the ciliary body, the IOP will cause that portion of the sclera to bulge outward, thereby increasing the diameter of the ciliary body and increasing the distance of the ciliary body from the lens. Any

method of weakening the structure of the sclera is suitable. For example enzymatic degradation of the collagen by collagenase may be employed. The collagenase may be carefully injected in to the appropriate region of the sclera or may be applied topically. Equivalent enzymes or other chemical treatments that weaken the collagen of the sclera can also be used. Certain antimitotic drugs such as mitomycin are known to cause a softening of the sclera (scleromalacia), and these drugs can be applied to the region of the sclera adjacent to the ciliary body, either topically or by injection, to effect the desired weakening of the sclera. Other antimitotic pharmaceutical agents, e.g., methotrexate, azaribine, 6-mercaptopurine, 5-fluorouracil, daunorubicin, doxorubicin, cytarabine, the vinca alkaloids and the like, can also be applied to the sclera to weaken it and permit it to be expanded by the intraocular pressure.

Alternatively, the sclera in the region of the ciliary body may be weakened by surgical means. The sclera may be thinned or weakened by the surgical removal of a portion of its collagenous substance, as, for example by ablating a portion of the thickness of the sclera. This thinning can be accomplished by paring or by abrading the surface or by ablating the surface with laser irradiation. The sclera can also be weakened by incisions carefully placed at appropriate angles in the region overlying

the ciliary body. The diameter of the sclera overlying the ciliary body can also be increased by making a complete periglobular incision and grafting into the incision appropriate tissue and/or physiologically acceptable structural material to increase the dimensions of the sclera. Thus an artificial scleral alloplant made of purified human collagen may be engrafted into such an incision. Other known biocompatible materials, e.g., poly(ethylene terephthalate), that are conventionally used in the construction of prosthetic devices may also be used for engrafting into such an incision. It is also possible to excise a small strip of sclera from the region overlying the ciliary body and replace it with a scleral alloplant as described above to provide an appropriate increase in the diameter of this region.

Alternatively the sclera in the region overlying the ciliary body can be weakened by irradiation with a laser beam to decompose partially the collagen fibers. Suitable lasers include those conventionally used in ocular surgery such as carbon dioxide lasers, helium-neon lasers, helium-cadmium lasers, argon ion lasers, krypton ion lasers, xenon lasers, nitrous oxide lasers, iodine lasers, holmium doped yttrium-aluminum garnet (YAG) lasers, excimer lasers, chemical lasers, harmonically oscillated lasers, dye lasers, nitrogen lasers, neodymium lasers, erbium lasers, ruby lasers, titanium-sapphire lasers, diode

lasers and the like.

FIGURE 10 shows a diagram of an exemplary laser 1000 of the type capable of treating various eye diseases in accordance with the principles of the present invention. Such eye diseases include presbyopia, hyperopia, primary open angle glaucoma, and ocular hypertension. Laser 1000 may be any suitably arranged laser, for instance, any of a carbon dioxide laser, a helium-neon laser, a helium-cadmium laser, an argon ion laser, a krypton ion laser, a xenon laser, a nitrous oxide laser, iodine laser, a holmium doped yttrium-aluminum garnet (YAG) laser, an excimer laser, a chemical laser, a harmonically oscillated laser, a dye laser, a nitrogen laser, a neodymium laser, an erbium laser, a ruby laser, a titanium-sapphire laser and a diode laser.

Laser 1000 is operable to weaken the sclera of an eye in the region of the ciliary body to thereby increase the effective working distance of the ciliary muscle of the eye and increase the amplitude of accommodation of the eye, all in accordance with the principles of the present invention.

Exemplary laser 1000 illustratively includes a power supply 1010, laser beam generator 1020 and a controller 1030. Exemplary power supply 1010 supplies power to laser 1000. Exemplary laser beam generator 1020 is operable to generate a narrow coherent beam of radiation. Exemplary controller 1030 is operable to

control the intensity of the laser beam generated. The laser beam may be one of ionizing radiation or non-ionizing radiation.

Laser 1000 is operable to weaken the sclera of the eye in the region of the ciliary body, for instance, by (i) abrading the sclera with laser irradiation, (ii) ablating the sclera with laser irradiation, (iii) incising the sclera with laser irradiation, (iv) incising the sclera at select angles with laser irradiation, and (v) decomposing partially collagen fibers in the sclera.

Exemplary laser 1000 is illustrated with three stages. Exemplary stage 1: in a laser, energy is stored in a "lasing" medium, which may be a solid, liquid or gas; the energy excites atoms in the medium, raising them to a high-energy state such that an excited atom releases a light ray (here, electrons in an electric current excite the gas atoms). Exemplary Stage 2: a ray of light from the excited atom strikes another excited atom, causing it also to emit a light ray; these light rays strike more excited atoms, and the process of light production grows, such that mirrors at the ends of the tube reflect the light rays so that more and more excited atoms release light. Exemplary Stage 3: as each excited atom emits a light ray, the new ray vibrates in step with the ray that strikes the atom; all the rays are in step, and the beam becomes bright enough to pass through the

semi-silvered mirror and leave the laser; the energy is as laser light.

Turning to FIGURE 11, shown is an exemplary flow diagram (generally designated 1100) of an exemplary method of operating a laser in accordance with the principles of the present invention. The discussion of FIGURE 11 is made concurrently with reference to FIGURE 10 and laser 1000.

Exemplary method 1100 operates laser 1000 to treat presbyopia, hyperopia, primary open angle glaucoma and ocular hypertension. Initially laser 1000 is enabled, causing laser beam generator 1020 to generate a laser beam whose intensity is controlled by controller 1030 (process step 1110). Laser 1000 is used to irradiate the sclera of an eye in the region of the ciliary body in accordance with the principles of the present invention to thereby weaken the sclera of the eye and to increase the effective working distance of the ciliary muscle of the eye (Step 1120).

This step of irradiating the sclera of an eye in the region of the ciliary body may comprise (i) abrading the sclera with laser irradiation; (ii) ablating the sclera with laser irradiation; (iii) incising the sclera with laser irradiation (including at select angles); and (iv) decomposing partially collagen fibers in the sclera.

Any irradiative treatment with ionizing or non-ionizing radiation that weakens the sclera may be used. For example irradiation with electrons, protons, or x-rays and the like, or irradiation with ultrasonic waves or the like can be used. Thermal burning and/or scarring in the appropriate area may also be used to induce an enlargement of the sclera in the area adjacent to the ciliary body.

Treatments designed to weaken the sclera in the region overlying the ciliary body can also be combined with application of the scleral expansion band of the invention. For example, the sclera can be treated with collagenase, mitomycin, or other antimitotic agent, as described above and the scleral band subsequently applied and fastened to the sclera. The band itself, its components and/or the sutures may also be coated or impregnated with the sclera-weakening agents whereby they can come into contact with the sclera and exercise their effect when the band is applied. In some cases the band may be later removed to leave the patient with a suitably expanded sclera.

Just as the distance between the ciliary body and the equator of the lens can be increased by expanding the sclera and ciliary body, the distance can be maintained and the progress of presbyopia arrested by stopping the growth of the crystalline lens. While such a treatment cannot reverse the course of

presbyopia, it can arrest the progress of the symptoms, and is appropriate for treatment of patients in whom the presbyopia has not progressed very far. The growth of the lens can be arrested by administration of pharmaceutical compounds which stop cell division and growth. For example, colchicine can be administered to prevent cell division, thereby stopping the growth of the lens. Conventional antimitotic drugs may also be used to arrest the growth of the lens. Such drugs are well known and include, for example, methotrexate, azaribine, 6-mercaptopurine, 5-fluorouracil, daunorubicin, doxorubicin, cytarabine, the vinca alkaloids and the like. Such drugs may be applied topically or by injection into the appropriate structure of the eye where they will come into contact with the lens and exercise their pharmacological activity. If the drugs are sufficiently free of side effects, they may also be administered systemically, either by mouth or parenterally. The growth of the lens may also be arrested by physical treatments directed at the newly forming cells in the epithelium of the lens, particularly in the equatorial region of the lens. Treatments that prevent further division of the cells are appropriate for preventing further lens growth. Thus, the epithelial cells may be heated by laser radiation or ultrasonic irradiation, or inactivated by laser irradiation with a laser capable of directly disrupting chemical

bonds within the structures of the cells. Sharply focused laser beams or irradiation with microscopic diode lasers positioned close to the equator of the lens are suitable for applying this radiation. Irradiation with electrons, protons, x-rays or the like may also be used to stop the further division of the epithelial cells of the lens. These treatments should be directed only to the portion of the lens structures that are composed of cells capable of dividing and should not be directed toward the substance of the lens where they might provoke the formation of cataracts

Surgical methods that work more directly on the ciliary muscle may also be used to increase the effective working distance of the muscle. The body of the muscle itself may be shortened, for example by scarring induced by irradiation with suitable laser beams or beams of ionizing or non-ionizing radiation such as ultrasound or electron or proton beams or x-rays. The effective working range of the muscle may also be increased by moving its insertions to increase the distance between them. The ciliary muscle is inserted anteriorly into the scleral spur and posteriorly into the choroid. Treatment of either of these insertions to cause them to move apart from the complementary insertion will increase the effective working range of the ciliary muscle and improve the amplitude of accommodation according to the invention. Selective scarring of adjacent tissue

planned to cause retraction of either insertion of the ciliary muscle is effective to accomplish this result. The scarring can be accomplished by thermal or radiative treatment of the tissue by the means and methods generally outlined above.

The method of the invention which increase the amplitude of accommodation may also be of benefit in treatment of hyperopia in certain patients. Some youthful hyperopes can achieve relatively normal vision by compensating for their hyperopia through the natural accommodative ability of the eye. However, as this ability declines with age, they find that it becomes more difficult to attain normal vision by this process, and they begin to experience headaches and other symptoms, even at an age somewhat less than usual for the onset of presbyopia. Evidently, increasing the amplitude of accommodation by the method of this invention would be useful in restoring the ability of these patients to compensate for their hyperopia.

The method of this invention also has utility in the treatment of primary open-angle glaucoma, which shows a correlation with age in certain individuals. It has been found that, in general, IOP exhibits a linear increase with increasing age. (Armaly, M.F., On the distribution of applanation pressure I. Statistical features and the effect of age, sex, and family history of glaucoma, Archives of Ophthalmology, Vol. 73, pp. 11-

18 (1965).) Among the general population is found a group of individuals who develop abnormally high intraocular pressures as a result of primary open angle glaucoma, a disease which is one of the most prevalent causes of blindness in the world. According to the theory of this invention, the linear increase in IOP with age is a direct result of the decrease in distance between the lens equator and the ciliary muscle and the resulting linear decrease in the effective pull of the ciliary muscle. Since the ciliary muscle inserts into the trabecular meshwork, the decrease in pull will decrease the size of the trabeculum and/or the drainage pores and result in a linear increase of intraocular pressure with age. In this view, the patients who develop primary open angle glaucoma may have a congenital predilection to narrower pores and/or smaller trabecular meshwork, so that when the ability of the ciliary muscle to exert force declines, after the age of 40 or thereabouts, they tend to develop excessively elevated IOP.

The method of the invention which increases the effective working distance of the ciliary muscle, and thereby increases the force that it can exert when it contracts, restores the level of force which the ciliary muscle exerts on the trabecular meshwork to a value characteristic of a more youthful eye. In this way it is expected that the tendency of an eye that is disposed to

develop primary open angle glaucoma as it ages would be overcome and the onset of this disease would be prevented or at least postponed.

The ability of the ciliary muscle to exert tension on the lens by means of the zonules can also be increased by shortening the zonules, a procedure which increases the effective working range of the ciliary muscle. This shortening can be produced by heating the zonules by ultrasonic irradiation or laser irradiation. The zonules may also be treated with electrons, protons, x-rays and the like which may cause changes in the structure of the zonules resulting in shortening. The shortening of the zonules may also be brought about by application of chemical compounds that act to cause a shrinkage of the collagenous zonules.

The invention will be illustrated by the following examples which are intended for illustration only and are not to be interpreted as limiting the claims.

EXAMPLE 1

This example illustrates the feasibility of increasing the diameter of the ciliary body by suturing an external band to the sclera.

Human cadaver eyes were selected for experimentation. The diameter of the sclera was measured using a shadow graph at

distances of 1.5 millimeters and 3.5 millimeters from the limbus. The diameters were found to be 16.2 mm and 20 mm respectively. Bands were made from medical grade poly(methyl methacrylate) having a low frustoconical shape and a radial thickness of 0.5 mm. The internal diameter of the larger (posterior) side was 20 mm, and the smaller (anterior) diameters varied from 14.5 mm to 18.0 mm in 0.25 mm steps. A band was selected having a major diameter of 20 mm and a minor diameter of 18.0 mm. The band was placed on the sclera of a human cadaver eye so that the 18.0 mm diameter end of the band was 1.5 mm from the limbus and the 20 mm diameter end was 3.5 mm from the limbus. The band was sutured through the holes with 16 interrupted 6-0 polyester (Mersilene, Ethicon, Inc.) stitches to the sclera. This resulted in a clearly observable stretching of the sclera in the region of the ciliary body. The pupil became dilated by about 1.5 mm. Since the iris inserts into the ciliary body, the pupillary dilation demonstrated that the induced scleral stretching was also moving the ciliary body outward, thereby increasing its diameter and its distance from the equator of the lens.

EXAMPLE 2

This example illustrates the treatment of presbyopia in patients.

Following informed consent, six presbyopic patients with otherwise normal eyes, except for minimal refractive errors, had scleral expansion bands of the invention sutured to the sclera in the region of the ciliary body. Their age ranged from 47 to 60 years, there were three males and three females, and their preoperative amplitude of accommodation varied from 1.3 to 2.7 diopters. The ophthalmological examination including biomicroscopy was normal. Following local infiltration into the conjunctive with prilocaine HCl for injection (Citanast (Astra), 40 mg/ml), a 360 degree limbal based peritomy was performed and the sclera was cleaned of Tenon's capsule. Using vernier calipers, a distance of 1.5 mm posterior to the limbus was measured from the limbus and the scleral diameter was measured at that location. A band of the type made in Example 1 was selected having a minor diameter of from 0.5 mm to 1.5 mm greater than the measured diameter of the sclera. The band was sutured to the sclera with 16 interrupted 6-0 polyester (Mersilene, Ethicon, Inc.) stitches. The patients were given antibiotic-steroid drops to use for five days. Postoperatively, the patients were followed daily for five days and then weekly. The results are presented in Table 1 below.

TABLE 1

Preoperative and Postoperative Amplitude of Accommodation

Patient No.	Age	Sex	Preoperative Near Point	Preoperative Amplitude of Accommodation	Postoperative Near Point	Postoperative Amplitude of Accommodation
	(yr)		(cm)	(diopters)	(cm)	(diopters)
1	55	M	75	1.3	9	11.1
2	50	F	45	2.2	10	10.0
3	47	F	37	2.7	16	6.25
4	56	M	56	1.7	9	11.1
5	60	F	38	2.6	12	8.3
6	46	M	40	2.5	17	5.8

The invention having now been fully described, it should be understood that it may be embodied in other specific forms or variations without departing from its spirit or essential characteristics. Accordingly, the embodiments described above are to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are intended to be embraced therein.

REDLINED COPY

13938-00009

PATENT APPLICATION

TITLE: SEGMENTED SCLERAL BAND FOR TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS

RELATIONSHIP TO OTHER APPLICATIONS

This application is a continuation-in-part of copending application Serial No. 08/462,649, filed June 05, 1995, which is a divisional of U.S. application Serial. No. 08/139,756, filed, October 22, 1993, now U.S. Patent No. 5,489,299, which is a divisional of U.S. application Serial No. 07/913,486, filed July 15, 1992, now U.S. Patent No. 5,354,331.

~~BACKGROUND OF THE INVENTION~~

1. Field of the Invention:

This invention relates to methods of treating presbyopia, hyperopia, primary open angle glaucoma and ocular hypertension and more particularly to methods of treating these diseases by increasing the effective working distance of the ciliary muscle. The invention also relates to increasing the amplitude of accommodation of the eye by increasing the effective working range of the ciliary muscle and to ~~prosthetic devices for achieving such increased amplitude of accommodation.~~

~~2. Brief Description of the Prior Art:~~

In order for the human eye to have clear vision of objects at different distances, the effective focal length of the eye must be adjusted to keep the image of the object focused as sharply as possible on the retina. This change in effective focal length is known as accommodation and is accomplished in the eye by varying the shape of the crystalline lens. Generally, in the unaccommodated emmetropic eye the curvature of the lens is such that distant objects are sharply imaged on the retina. In the unaccommodated eye, near objects are not focused sharply on the retina because their images lie behind the retinal surface. In order to visualize a near object clearly, the curvature of the crystalline lens is increased, thereby increasing its refractive power and causing the image of the near object to fall on the retina.

The change in shape of the crystalline lens is accomplished by the action of certain muscles and structures within the eyeball or globe of the eye. The lens is located in the forward part of the eye, immediately behind the pupil. It has the shape of a classical biconvex optical lens, i.e., it has a generally circular cross section having two convex refracting surfaces, and is located generally on the optical axis of the eye, i.e., a straight line drawn from the center of the cornea to the macula in the retina at the posterior ~~portion of the globe. In the unaccommodated human eye the~~

~~curvature of the posterior surface of the lens, i.e., the~~ surface adjacent to the vitreous body, is somewhat greater than that of the anterior surface. The lens is closely surrounded by a membranous capsule that serves as an intermediate structure in the support and actuation of the lens. The lens and its capsule are suspended on the optical axis behind the pupil by a circular assembly of very many radially directed elastic fibers, the zonules, which are attached at their inner ends to the lens capsule and at their outer ends to the ciliary body, a muscular ring of tissue, located just within the outer supporting structure of the eye, the sclera. The ciliary muscle is relaxed in the unaccommodated eye and therefore assumes its largest diameter. According to the classical theory of accommodation, originating with Helmholtz, the relatively large diameter of the ciliary muscle in this condition causes a tension on the zonules which in turn pulls radially outward on the lens capsule, causing the equatorial diameter of the lens to increase slightly and decreasing the anterior-posterior dimension of the lens at the optical axis. Thus, the tension on the lens capsule causes the lens to assume a flattened state wherein the curvature of the anterior surface, and to some extent the posterior surface, is less than it would be in the absence of the tension. In this state the refractive power of the lens is relatively low and the eye is focused for ~~clear vision of distant objects.~~

~~When the eye is intended to be focused on a near object,~~ the ciliary muscles contract. According to the classical theory, this contraction causes the ciliary muscle to move forward and inward, thereby relaxing the outward pull of the zonules on the equator of the lens capsule. This reduced zonular tension allows the elastic capsule of the lens to contract, causing an increase in the antero-posterior diameter of the lens (i.e., the lens becomes more spherical) resulting in an increase in the optical power of the lens. Because of topographical differences in the thickness of the lens capsule, the central anterior radius of curvature decreases more than the central posterior radius of curvature. This is the accommodated condition of the eye wherein the image of near objects falls sharply on the retina.

Presbyopia is the universal decrease in the amplitude of accommodation that is typically observed in individuals over 40 years of age. In the person having normal vision, i.e., having emmetropic eyes, the ability to focus on near objects is gradually lost, and the individual comes to need glasses for tasks requiring near vision, such as reading.

According to the conventional view the amplitude of accommodation of the aging eye is decreased because of the loss of elasticity of the lens capsule and/or sclerosis of the lens with age. Consequently, even though the radial tension on the zonules is relaxed by contraction of the ciliary muscles, ~~the lens does not assume a greater curvature.~~

~~According to the conventional view, it is not possible by any~~ treatment to restore the accommodative power to the presbyopic eye. The loss of elasticity of the lens and capsule is seen as irreversible, and the only solution to the problems presented by presbyopia is to use corrective lenses for close work, or bifocal lenses, if corrective lenses are also required for distant vision.

Certain rings and/or segments have been used in ocular surgery for various purposes. Rings and/or segments of flexible and/or elastic material, attached or prepared in situ by fastening the ends of strips of the material around the posterior portion of the globe, posterior to the pars plana (over the underlying retina), have been used to compress the sclera in certain posterior regions. Supporting rings of metal, adapted to fit the contour of the sclera have been used as temporary supporting structures during surgery on the globe. However, none of these known devices has been used for surgical treatment of presbyopia, and none has been adapted to the special needs of prosthetic devices used in treating presbyopia.

A scleral band adapted to be fastened to the sclera of the eye in the region of the ciliary body in order to expand the sclera in that region and thereby increase the working distance of the ciliary muscle is described in applicant's U.S. Patent 5,354,331, the entire disclosure of which is ~~incorporated herein by reference. The scleral band of that~~

pate~~nt is manufactured as a single unitary device that is~~ placed on the surface of the sclera and fastened thereto, e.g., by suturing. Although the band is effective, alternative designs are possible that permit greater flexibility in installing the scleral band.

Accordingly, a need has continued to exist for a scleral band for treating presbyopia and other eye disorders that allows the surgeon the opportunity of other methods of installing or implanting the band.

SUMMARY OF THE INVENTION

An alternative design for a scleral band that can be implanted to treat presbyopia and other eye disorders is found in the band of this invention wherein a scleral band comprises a plurality of segments that can be assembled on the eye to form a complete scleral band. The invention also comprises a method for installing such a segmented band comprising the steps of forming tunnels in the substance of the sclera in the region overlying the ciliary body, inserting segments of the segmented band into the tunnels, and uniting the ends of the segments to form a unitary scleral band.

Accordingly, it is an object of the invention to provide a treatment for presbyopia.

A further object is to provide a treatment for presbyopia by increasing the effective working distance of the ciliary ~~muscle in the presbyopic eye~~.

~~A further object is to provide a treatment for presbyopia~~ by increasing the radial distance between the equator of the crystalline lens and the ciliary body.

A further object is to provide a treatment for presbyopia by implanting in the sclera in the region overlying the ciliary body a generally rigid band whereby the sclera is expanded in the region of the ciliary body.

A further object is to provide a segmented scleral band that can be assembled on the eye to provide a generally rigid band.

A further object is to provide a segmented scleral band having segments that can be inserted into tunnels prepared in the substance of the sclera and assembled thereafter to provide a generally rigid band.

A further object is to provide a treatment for hyperopia.

A further object is to provide a treatment for primary open angle glaucoma.

A further object is to provide a treatment for ocular hypertension.

A further object is to provide a treatment for increasing the amplitude of accommodation of the eye.

Further objects of the invention will become apparent from the description of the invention which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

~~Figure 1 illustrates a front elevational view of human~~

~~eye with a scleral expansion band of the invention implanted~~ therein.

Figure 2 shows a cross-section of the eye shown in Figure 1 along the line 2-2.

Figure 3 shows an enlarged view of the cross section of Figure 4 in the region indicated by the circle 3.

Figure 4 shows a front elevational view of the segmented scleral band of the invention.

Figure 5 shows a side elevational view of the band.

Figure 6 shows an isometric view of the band.

Figure 7 shows a plan view of a segment of the band.

Figure 8 shows an end view of a band segment as indicated by line 8-8 in Figure 7.

Figure 9 shows an end view of a band segment as indicated by line 9-9 in Figure 7.

Figure 10 shows a cross-sectional view of a band segment along line 10-10 in Figure 7.

Figure 11 shows a cross section of the fused tongue and groove portion of the segmented scleral band along lines 11-11 in Figure 4.

DETAILED DESCRIPTION OF THE INVENTION AND PREFERRED EMBODIMENTS

This invention is based on a theory of presbyopia different from the classical theory of Helmholtz. Although ~~the scope of the invention is not to be bound or limited by~~

~~the inventor's theory, it is the inventor's view that the~~ presbyopic loss of accommodation is due to decreased working distance of the ciliary muscle. This theory is described in more detail in Patent No. 5,354,331, referenced above and incorporated herein by reference. Consequently, according to the invention, presbyopia is treated by increasing the effective working distance of the ciliary muscle. This is accomplished by increasing the distance between the ciliary muscle and the lens equator by increasing the diameter of the sclera in the region of the ciliary body.

According to the invention, the effective working distance of the ciliary muscle is increased by implanting in tunnels or pockets surgically formed within the tissue of the sclera of the eye a plurality of scleral band segments. The segments are then joined to form a complete scleral expansion band implanted at least partially within the sclera of the eye. The completed scleral expansion band is sized to be slightly larger than the sclera in the region of the ciliary body. Accordingly, the scleral expansion band exerts an outward traction on the sclera, thereby expanding it slightly generally in the plane of the crystalline lens. The scleral expansion also expands, i.e., increases the diameter, of the ciliary body which lies immediately inside or beneath the sclera and is anatomically attached thereto.

The relevant anatomy of the eye for understanding the operation ~~of the scleral expansion band of the invention and~~

~~for locating the scleral pockets may be seen by reference to~~ Figures 1-3. Figure 1 shows an eye 100 provided with a scleral expansion band according to the invention. The outermost layer of the eye 100 comprises the white, tough sclera 102 which encompasses most of the globe and the transparent cornea 104, which constitutes the anterior segment of the outer coat. The circular junction of the cornea and sclera is the limbus 106. Within the globe of the eye, as illustrated in the cross-section of Figure 2, taken along line 2-2 in Figure 1, the crystalline lens 108 is enclosed in a thin membranous capsule and is located immediately posterior to the iris 112, suspended centrally posterior to the pupil 114 on the optical axis of the eye. The lens 108 is suspended by zonules 115 extending between the lens capsule at the equator 110 of the lens 108 and the ciliary body 116. The ciliary body 116 lies just under the sclera 102 (i.e., just inwardly of the sclera 102) and is attached to the inner surface of the sclera 102. As may be seen in Figure 2, the ciliary body 116 lies generally in a plane 130 defined by the equator 110 of the lens 108. The plane 130 can also be extended to intersect the sclera 102 whereby it forms a generally circular intersection located about 2 millimeters posterior to the limbus 106.

According to the invention a generally outwardly directed traction is exerted on the sclera in the region of the ciliary body to expand the sclera 102 in that region. ~~This expansion~~

~~of the sclera 102 produces a corresponding expansion of the~~ attached ciliary body 116 and moves the ciliary body 116 outwardly away from the equator of the lens 108, generally in the plane 130 of the equator 110 of the lens 108. The sclera 102 is preferably expanded approximately in the plane of the equator of the lens 108. However, any expansion of the sclera 102 in the region of the ciliary body 116, i.e., in the region or zone of the sclera extending somewhat anterior or posterior to the plane of the equator 110 of the lens 108 is within the scope of the invention, provided that such expansion of the sclera 102 moves the ciliary body 116 away from the equator 110 of the lens 108. Typically, the expansion of the sclera will be accomplished in the region or zone from about 1.5 millimeters anterior to the plane 130 of the equator of the lens 108 to about 2.5 millimeters posterior to that plane, i.e., from about 0.5 millimeters to about 4.5 millimeters posterior to the limbus 106. Accordingly, the scleral pocket or tunnel 120 will be located in that region or zone of the sclera.

The scleral band 200 of the invention is assembled from a plurality of segments 202. The assembled band 200, as seen in Figures 1, 4, 5 and 6, has an anterior rim 226, a posterior rim 228 and a web structure 230 connecting the two rims. In order to apply the desired outward traction on the sclera at the region of the ciliary body, at least a circumferential ~~portion of the band, i.e., either the anterior rim 226, the~~

~~posterior rim 228, or the connecting web structure 230, is~~ designed to have a diameter, when the band is assembled, slightly greater than the diameter of the sclera at the location where the band is implanted. Of course, the entire band may have a size slightly greater than the sclera. The outward tension on the sclera is applied in the region of the ciliary body as illustrated in Figures 2, which shows a cross-section of the eye with the scleral band 200 of the invention implanted, and in Figure 3, which shows a detail of the cross-section of the eye as indicated by the dashed circle 3 in Figure 2. The scleral expansion band 200 is shown within the scleral tunnel 120, which has a base 126, an outer flap 128, an anterior margin 122 and a posterior margin 124. The scleral band 200 within the tunnel or pocket 120 exerts an outward force on the outer flap 128 of the scleral pocket 120 because the band is generally larger in diameter than the sclera at the zone where the band is implanted. The outer flap 128 then transfers the outward traction via its connection to the rest of the sclera at the anterior margin 122 and posterior margin 124. Thereby, the sclera is expanded in a zone surrounding the ciliary body 116 and causes the attached ciliary body 116 to be increased in diameter as well. Accordingly, the scleral pockets or tunnels 120, which resemble belt loops through which the scleral expansion band is threaded, are located in the region of the ciliary body, ~~and generally close to a plane defined~~ by the equator of the

~~crystalline lens. Thus, the scleral expansion band is~~ positioned with respect to the antero-posterior axis of the globe of the eye, such that it will exert a traction on the sclera that will produce a radial expansion of the ciliary body located just beneath or within the sclera.

The scleral band and its segments are illustrated in Figures 4-11 of the drawings wherein the reference numerals refer to the same parts throughout. The scleral band 200 is comprised of a plurality of segments 202. The band 200 is designed to be applied to the sclera of the eye by forming scleral pockets or tunnels in the sclera, then passing a segment 202 through each of the tunnels and fastening the ends of the segments together to form a complete band.

Accordingly, each segment 202, as shown in Figures 9-10, has an anterior edge 204, a posterior edge 206, an outer surface 208, an inner surface 210, and two lateral ends 212 and 214. Although the illustrated embodiment of the segment shows a continuous web 230 of material connecting the anterior edge 204 and the posterior edge 206, the connecting structure 230 need not be such a continuous structure. Any structure, e.g., a web having apertures, or a lattice structure, is suitable, provided that the connecting structure has sufficient strength to keep the anterior edge 204 and the posterior edge 206 in their relative positions to provide the necessary rigidity to the assembled band 200. In the ~~illustrated embodiment, one lateral end 212 of each segment~~

~~202 is provided with a tongue 216, and the other lateral end~~ 214 is provided with a corresponding groove 218. After the segments are inserted through the scleral tunnels, the ends 212 and 214 are exposed as shown in Figure 1. Each tongue 216 is then inserted into its corresponding groove 218, and the tongues 214 are then fastened in place within the grooves 218 to form the complete scleral band as shown in Figures 1, 4, and 5. Any means of fastening the segments 202 together is suitable. The segments may be bonded with an adhesive or welded or fused together, or a mechanical fastener, such as a screw or rivet can be used to fasten the ends of the segments 202 together. A preferred method of fastening the segments 202 together, when the segments are made from a preferred plastic material such as poly(methyl methacrylate) is to weld or fuse the lower surface 218 of the tongue 216 to the bottom 222 of the groove 220 by ultrasonic welding. The ultrasonic welding can be accomplished by conventional techniques. For example, the tongue 216 can first be positioned in the groove 220, then a support shoe is inserted under the end 214 of the segment 202 and an ultrasonic welding tool is applied to the tongue 216 for a time sufficient to form a fused welded area 224 (Figure 11).

The segments 202 are typically dimensioned to fit snugly in the scleral tunnels. A typical segment will have a width of about 2 millimeters and a thickness of about ~~0.25 millimeters. The length of a typical segment, measured~~

~~along the circumference from one end of the main body of the~~ segment 202 to the other will be about 13 millimeters. The tongue will be about 3 millimeters in length. The skilled practitioner will understand that the dimensions will be adapted to the particular eye into which the scleral band is to be implanted. In particular, an assortment of lengths is typically made available to the surgeon so that segments can be selected that, when assembled on the globe of the eye, the completed scleral expansion band will be of the proper size to exert the desired outward traction on the sclera and ciliary body. If the segments 202 are made of a material that has some flexibility perpendicular to the surface thereof, e.g., a synthetic resin material, the segments can be made flat and curved to match the curvature of the globe of the eye when the band is implanted. If the band is made of a more rigid material it is preferable to form an appropriate curve before insertion. A typical segment of the preferred embodiment as illustrated will have a radius of curvature of the anterior rim of about 8.3 millimeters, and a corresponding radius of curvature of the posterior rim of about 10.3 millimeters. The radii of the rims can be accommodated to the particular dimensions of the eye into which the band is to be implanted.

Although the illustrated embodiment shows a tongue-and-groove design for joining the segments 202 that form the scleral band 200, the skilled practitioner will understand ~~that other designs can be used as well. For example a simple~~

~~butt joint effected by adhesive joining or welding could be~~ used. Similarly, a lap joint or a tapered scarf joint can be used. Again one end of the segment 202 can be provided with a projection that fits into a recess or hole in end of the adjacent segment. The ends can be shaped to have complementary shapes that fit together much as a pieces of a jigsaw puzzle.

In practicing the method of the invention, the surgeon first locates the proper region or segment or zone of the sclera to be expanded by measuring a distance of preferably 2.0 millimeters posterior of the limbus. The scleral tunnels or pockets are then formed, preferably by the following procedure. At 2.5 millimeters clockwise and counterclockwise from each of the 45° meridians of the eye, and 2 millimeters posterior to the limbus, partial scleral thickness radial incisions, i.e., antero-posterior incisions, are made which are 2 millimeters long and 350 microns deep. Using a lamella blade the sclera is dissected until the partial thickness incisions are connected so that four scleral pockets or belt loops are made which have an anterior length of 5 millimeters, and a length extending generally axially of the eye of 2 millimeters. Thus, each pocket or belt loop is preferably centered over the 45° meridian of the eye. Each tunnel is directed generally circumferentially with respect to a circle defined generally by the intersection of the sclera with the ~~plane of the equator of the crystalline lens, although the~~

~~tunnels need not be exactly in that plane. A segment 202 of~~ the scleral band 200 is then inserted in each pocket so that the ends 212 and 214 of the segments 202 meet in the spaces between the pockets, as shown in Figure 1. The ends 212 and 214 of the segments 202 are then joined. In the illustrated embodiment the ends are joined by fitting the tongue 216 of one segment 202 into the groove 220 of the adjacent segment and fastening the tongue in the groove by ultrasonic welding or other joining technique as discussed above. The completed scleral band then produces symmetrical scleral expansion which will produce the desired result of increasing the effective working distance of the ciliary muscle.

The illustrated embodiment of the invention illustrates a preferred embodiment of the invention using use of four scleral tunnels and four scleral band segments. Fewer or more tunnels may be used at the surgeon's choice. It is not excluded that a single tunnel could be used with the segments of the band being joined through appropriate incisions.

The scleral band of the invention is made of a material that is sufficiently rigid to exert a force on the sclera sufficient to produce the radial expansion required by the method of the invention and that is physiologically acceptable for long-term implantation or contact with the ocular tissues. Such materials are well-known in the surgical art and include suitable metals, ceramics, and synthetic resins. Suitable ~~metals include titanium, gold, platinum, stainless steel,~~

~~tantalum, shape-memory alloys, and various surgically~~ acceptable alloys, and the like. Suitable ceramics may include crystalline and vitreous materials such as porcelain, alumina, silica, silicon carbide, high-strength glasses and the like. Suitable synthetic materials include physiologically inert materials such as poly(methyl methacrylate), polyethylene, polypropylene, poly(tetra-fluoroethylene), polycarbonate, silicone resins and the like. The segment may also be made of composite materials incorporating a synthetic resin or other matrix reinforced with fibers of high strength material such as glass fibers, boron fibers or the like. Thus, the segment may be made of glass-fiber-reinforced epoxy resin, carbon fiber-reinforced epoxy resin, carbon fiber-reinforced carbon (carbon-carbon), or the like. A preferred material for the segment 202 is surgical grade poly(methyl methacrylate).

The segment of the scleral band of the invention may be manufactured by any conventional technique appropriate to the material used, such as machining, injection molding, heat molding, compression molding and the like.

The use of the scleral band of the invention to expand the sclera in the region of the ciliary body and increase the working distance of the ciliary muscle may also be of benefit in treatment of hyperopia in certain patients. Some youthful hyperopes can achieve relatively normal vision by compensating ~~for their hyperopia through the natural accommodative ability~~

~~of the eye. However, as this ability declines with age, they~~ find that it becomes more difficult to attain normal vision by this process, and they begin to experience headaches and other symptoms, even at an age somewhat less than usual for the onset of presbyopia. Evidently, increasing the amplitude of accommodation by the method of this invention would be useful in restoring the ability of these patients to compensate for their hyperopia.

The method of this invention also has utility in the treatment of primary open-angle glaucoma, which shows a correlation with age in certain individuals. It has been found that, in general, intraocular pressure (IOP) exhibits a linear increase with increasing age. (Armaly, M.F., On the distribution of applanation pressure I. Statistical features and the effect of age, sex, and family history of glaucoma, Archives of Ophthalmology, Vol. 73, pp. 11-18 (1965)). Among the general population is found a group of individuals who develop abnormally high intraocular pressures as a result of primary open angle glaucoma, a disease which is one of the most prevalent causes of blindness in the world. According to the theory of this invention, the linear increase in IOP with age is a direct result of the decrease in distance between the lens equator and the ciliary muscle and the resulting linear decrease in the effective pull of the ciliary muscle. Since the ciliary muscle inserts into the trabecular meshwork, the ~~decrease in pull will decrease the size of the trabeculum~~

~~and/or the drainage pores and result in a linear increase of~~ intraocular pressure with age. In this view, the patients who develop primary open angle glaucoma may have a congenital predilection to narrower pores, protein deposition in the pores, and/or a smaller trabecular meshwork, so that when the ability of the ciliary muscle to exert force declines, after the age of 40 or thereabouts, they tend to develop excessively elevated IOP.

The use of the scleral band of the invention to increase the effective working distance of the ciliary muscle, and thereby increase the force that it can exert when it contracts, restores the level of force which the ciliary muscle exerts on the trabecular meshwork to a value characteristic of a more youthful eye. In this way it is expected that the tendency of an eye that is disposed to develop primary open angle glaucoma as it ages would be overcome and the onset of this disease would be prevented or at least postponed.

The invention having now been fully described, it should be understood that it may be embodied in other specific forms or variations without departing from its spirit or essential characteristics. Accordingly, the embodiments described above are to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the ~~appended claims rather than the foregoing description, and all~~

changes ~~which come within the meaning and range of equivalency of the claims are intended to be embraced therein.~~